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DATE MAILED: 09/16/2004

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/076,247 01/14/2002 Adolfo Goren P 0280702 1041 23873 **EXAMINER** 7590 09/16/2004 ROBERT W STROZIER, P.L.L.C COE, SUSAN D **PO BOX 429** ART UNIT PAPER NUMBER BELLAIRE, TX 77402-0429 1654

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Applic | ation No. | Applicant(s) | | |
|---|---|--|-----------|--------------|--|--|
| Office Action Summary | | 10/076 | | GOREN ET AL. | | |
| | | Examir | | Art Unit | | |
| | | Susan | | 1654 | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on <u>21 June 2004</u> . | | | | | |
| • | This action is FINAL . | s action is FINAL . 2b) This action is non-final. | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-39 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-39 are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | |

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DETAILED ACTION

1. Claims 1-38 are currently pending. Please take notice of the election of species requirement beginning on page 3. To be fully responsive, applicant must fulfill this requirement.

2. This new restriction requirement contains an additional election of species requirement between the different species of *Allium*. These species are clearly considered by applicant to be separately patentable over each other, as evidenced by arguments presented by applicant in the response submitted June 21, 2004.

Election/Restrictions

- 3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 14, 17, 25, and 26, drawn to a method of treating HIV or AIDS, classified in class 424, subclass 754.
 - II. Claims 8-13, drawn to a method of treating viral infection, classified in class 424, subclass 754.
 - III. Claim 15, drawn to a method for promoting appetite and/or weight gain, classified in class 424, subclass 754.
 - IV. Claims 16 and 18, drawn to a method for stimulating and/or modulating the immune system, classified in class 424, subclass 754.
 - V. Claim 19, drawn to a method for enhancing T-cell function, classified in class424, subclass 754.

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VI. Claims 20-24, drawn to a method for treating microbial infection, classified in class 424, subclass 754.

VII. Claims 27-38, drawn to a method for making a *Allium* extract and the product made, classified in class 424, subclass 754.

The inventions are distinct, each from the other because of the following reasons:

- 4. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. Each invention treats a different ailment. Therefore, the effect of each invention is distinct.
- 5. Inventions VII is related to any of Inventions I-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a different purpose, such as the such of *Allium cepa* as a spice.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter in the non-patent literature, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

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A) Allium species selected from A. cepa, A. ampeloprasum, A. fistulosa, and A. schoenoprasum; and

B) type of virus selected from influenza, herpes, hepatitis, parvovirus, distemper, RSV, CMV, rhinovirus, rhabdovirus, papillomavirus, Epstein Barr, or foot and mouth disease.

If applicant elects group II, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 8, 9, and 11-13 are generic.

An example of a proper election is: Group II, species A: A. cepa; species B: influenza.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe, Examiner September 14, 2004